

General

Guideline Title

Diagnosis and treatment of adult isthmic spondylolisthesis.

Bibliographic Source(s)

North American Spine Society (NASS). Diagnosis and treatment of adult isthmic spondylolisthesis. Burr Ridge (IL): North American Spine Society (NASS); 2014. 87 p. [488 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The grades of recommendations (A-C, I) and levels of evidence (I-V) are defined at the end of the "Major Recommendations" field.

Definition and Natural History

What is the best working definition of isthmic spondylolisthesis?

Isthmic spondylolisthesis is the anterior translation of one lumbar vertebra relative to the next caudal segment as a result of an abnormality in the pars interarticularis. When symptomatic, this causes a variable clinical syndrome of back and/or lower extremity pain, and may include varying degrees of neurologic deficits at or below the level of the injury. Work Group Consensus Statement

What is the likelihood that spondylolysis (unilateral and/or bilateral, identified in adolescence or adulthood) will progress to become a symptomatic spondylolisthesis?

Spondylolisthesis occurs in 40% to 66% of patients with bilateral spondylolysis. Spondylolisthesis is unlikely to occur in patients with unilateral spondylolysis. *Grade of Recommendation: B*

Diagnosis and Imaging

What are the most appropriate physical examination findings consistent with the diagnosis of isthmic spondylolisthesis in adult patients?

There is insufficient evidence to make a recommendation for or against the use of palpation in the physical exam diagnosis of adult patients with isthmic spondylolisthesis. *Grade of Recommendation: I (Insufficient Evidence)*

Approximately half of adult patients with symptomatic isthmic spondylolisthesis will have a positive straight leg test on examination. *Grade of Recommendation: B*

In adult patients, what symptoms or clinical presentation are associated with the diagnosis of isthmic spondylolisthesis?

In adult patients with symptomatic isthmic spondylolisthesis, most patients present with low back pain and at least half present radicular lower extremity pain. *Grade of Recommendation: B*

What are the most appropriate diagnostic tests for adult isthmic spondylolisthesis?

There is a relative paucity of high quality studies on imaging in adult patients with isthmic spondylolisthesis. It is the opinion of the work group that in adult patients with history and physical examination findings consistent with isthmic spondylolisthesis, standing plain radiographs, with or without oblique views or dynamic radiographs, be considered as the most appropriate, noninvasive test to confirm the presence of isthmic spondylolisthesis. In the absence of a reliable diagnosis on plain radiographs, computed tomography (CT) scan is considered the most reliable diagnostic test to diagnose a defect of the pars interarticularis. In adult patients with radiculopathy, magnetic resonance imaging (MRI) should be considered. Work Group Consensus Statement

MRI is suggested to identify neuroforaminal stenosis in adult patients with isthmic spondylolisthesis. Grade of Recommendation: B

There is insufficient evidence to make a recommendation for or against the use of MRI to differentiate isthmic versus degenerative spondylolisthesis in adult patients. *Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to make a recommendation for or against the use of discography to evaluate adult patients with isthmic spondylolisthesis. *Grade of Recommendation: I (Insufficient Evidence)*

CT may be considered as an option to diagnose isthmic spondylolisthesis in adult patients. Grade of Recommendation: C

There is insufficient evidence to make a recommendation for or against the use of single-photon emission computerized tomography (SPECT) in evaluating isthmic spondylolisthesis in adult patients. *Grade of Recommendation: I (Insufficient Evidence)*

In adult patients, what is the relationship between the radiological grade of isthmic spondylolisthesis and expected clinical presentation?

A systematic review of the literature yielded no studies to adequately address this question.

How frequently do adult patients with isthmic spondylolisthesis have abnormal findings of their sagittal spinopelvic alignment, sacral alignment and spinopelvic parameters?

Adult patients with a diagnosis of isthmic spondylolisthesis have a higher pelvic incidence, sacral slope, pelvic tilt and lumbar lordosis compared to patients without isthmic spondylolisthesis. *Grade of Recommendation: B*

Outcome Measures for Medical/Interventional and Surgical Treatment

What are the appropriate outcome measures for the treatment of adult isthmic spondylolisthesis?

For information on outcome measures for spinal disorders, the North American Spine Society (NASS) has a publication entitled *Compendium of Outcome Instruments for Assessment and Research of Spinal Disorders*. To purchase a copy of the Compendium, visit https://webportal.spine.org/Purchase/ProductDetail.aspx?Product_code=68cdd1f4-c4ac-db11-95b2-001143edb1c1.

For additional information about the Compendium, please contact the NASS Research Department at nassresearch@spine.org.

Medical and Interventional Treatment

What is the role of pharmacological treatment in the management of isthmic spondylolisthesis?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

What is the role of manipulation in the treatment of isthmic spondylolisthesis?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

What is the role of steroid injections for the treatment of isthmic spondylolisthesis?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

What is the role of ancillary treatments such as bracing, traction, electrical stimulation and transcutaneous electrical stimulation (TENS) in the treatment of isthmic spondylolisthesis?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

What is the role of physical therapy/exercise in the treatment of isthmic spondylolisthesis?

There is insufficient evidence to make a recommendation for or against the use of physical therapy/exercise for the treatment of isthmic spondylolisthesis. *Grade of Recommendation: I (Insufficient Evidence)*

Does the degree of radiological grade, sagittal spinopelvic alignment, sacral and spinopelvic parameters, or the presence of dynamic instability in patients with isthmic spondylolisthesis affect the outcomes of patients treated with medical or interventional treatment?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

What is the long-term result of medical/interventional management of isthmic spondylolisthesis?

There is insufficient evidence to make a recommendation for or against the use of medical/interventional treatment for the long-term management of patients with isthmic spondylolisthesis. *Grade of Recommendation: I (Insufficient Evidence)*

Surgical Treatment

In adult patients, is surgical treatment more effective than medical/interventional treatment alone for the treatment of isthmic spondylolisthesis?

There is insufficient evidence to make a recommendation for or against the efficacy of surgical treatment as compared to medical/interventional alone for the management of adult patients with isthmic spondylolisthesis. *Grade of Recommendation: I (Insufficient Evidence)*

Does the addition of lumbar fusion, with or without instrumentation, to surgical decompression improve surgical outcomes in the treatment of adult patients with isthmic spondylolisthesis compared to treatment by decompression alone?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

Does the addition of instrumentation to decompression and fusion for adult patients with isthmic spondylolisthesis improve surgical outcomes compared with decompression and fusion alone?

In patients with low-grade isthmic spondylolisthesis, the addition of instrumentation may not improve outcomes in the setting of posterolateral fusion, with or without decompression. *Grade of Recommendation: B*

How do outcomes of decompression with posterolateral fusion compare with those for 360° fusion in the treatment of adult patients with isthmic spondylolisthesis?

Posterolateral fusion and 360° fusion surgeries are recommended to improve the clinical outcomes in adult patients with low grade isthmic spondylolisthesis. *Grade of Recommendation:* A

360° fusion is recommended to provide higher radiographic fusion rates compared to posterolateral fusion in adult patients with low grade isthmic spondylolisthesis. *Grade of Recommendation:* A

There is conflicting evidence whether 360° fusion provides better clinical outcomes than posterolateral fusion alone. *Grade of Recommendation: I (Insufficient/Conflicting Evidence)*

Does reduction with fusion result in better outcomes than fusion in situ in adult patients with isthmic spondylolisthesis?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

What is the role of stand-alone inter body fusion, for the purpose of indirect decompression, in the treatment of adult patients with isthmic

spondylolisthesis?

Anterior lumbar interbody fusion (ALIF) may be considered as an option to indirectly decompress foraminal stenosis in adult patients with low grade isthmic spondylolisthesis. *Grade of Recommendation:* C

How do outcomes from minimally invasive spinal surgery (for decompression and/or fusion) for the management of adult patients with isthmic spondylolisthesis compare with traditional/open techniques?

In adult patients undergoing ALIF, supplemental posterior percutaneous pedicle screws lead to shorter hospital stays, less operation room time and less blood loss compared to open posterior instrumentation. *Grade of Recommendation: B*

There is conflicting evidence whether in adult patients undergoing ALIF, supplemental posterior percutaneous pedicle screws lead to comparable clinical outcomes to those undergoing open posterior instrumentation. *Grade of Recommendation: I (Insufficient/Conflicting Evidence)*

How do outcomes of dynamic stabilization compare with fusion for the treatment of isthmic spondylolisthesis in adult patients?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

Does the degree of radiological grade, sagittal spinopelvic alignment, sacral and spinopelvic parameters, or the presence of dynamic instability in adult patients with isthmic spondylolisthesis affect the outcomes of patients treated with surgery?

There is insufficient evidence to make a recommendation regarding the degree of radiological grade, sagittal spinopelvic alignment, sacral and spinopelvic parameters, or the presence of dynamic instability on the outcomes of adult patients undergoing surgical treatment for isthmic spondylolisthesis. *Grade of Recommendation: I (Insufficient Evidence)*

Does the addition of fusion levels (cephalad, caudal or iliac) in the setting of a high grade isthmic spondylolisthesis in adult patients improve outcomes?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

What is the long-term result (four+ years) of surgical management of adult patients with isthmic spondylolisthesis?

In adult patients undergoing surgical treatment for isthmic spondylolisthesis, fusion is suggested to provide long term clinical improvements. *Grade of Recommendation: B*

There is insufficient evidence to indicate that fusion leads to improved long term outcomes as compared with a directed exercise program. *Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to recommend one surgical fusion technique over another to improve long term outcomes in adult patients undergoing surgical treatment for isthmic spondylolisthesis. *Grade of Recommendation: I (Insufficient Evidence)*

There is insufficient evidence to determine the clinical significance of adjacent segment degeneration on the long term outcomes of fusion. *Grade of Recommendation: I (Insufficient Evidence)*

Are the results of surgical management for adult patients with isthmic spondylolisthesis affected by the presence of scoliosis or concurrent deformity?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

Which prognostic factors have been associated with good or poor outcomes in the surgical management of adult patients with isthmic spondylolisthesis?

There is insufficient evidence to make a recommendation regarding which prognostic factors have been associated with good or poor outcomes. Grade of Recommendation: I (Insufficient Evidence)

Value of Spine Care

Which medical or interventional treatment method of isthmic spondylolisthesis is the most cost-effective?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

Is the surgical treatment of isthmic spondylolisthesis cost-effective compared to the medical and interventional therapies?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

Which surgical treatment method of isthmic spondylolisthesis is the most cost-effective?

There was no evidence to address this clinical question. Due to the paucity of literature addressing this question, the work group was unable to generate a recommendation.

Definitions

Levels of Evidence for Primary Research Question¹

		Types of Studies		
	Therapeutic Studies — Investigating the results of treatment	Prognostic Studies — Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies — Investigating a diagnostic test	Economic and Decision Analyses — Developing an economic or decision model
LevelI	 High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals Systematic review² of Level I RCTs (and study results were homogenous³) 	 High quality prospective study⁴ (all patients were enrolled at the same point in their disease with ≥80% follow-up of enrolled patients) Systematic review² of Level I studies 	 Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) Systematic review² of Level I studies 	 Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses Systematic review² of Level studies
Level II	 Lesser quality RCT (e.g., <80% follow-up, no blinding, or improper randomization) Prospective⁴ comparative study⁵ Systematic review² of Level II studies or Level 1 studies with inconsistent results 	 Retrospective⁶ study Untreated controls from an RCT Lesser quality prospective study (e.g., patients enrolled at different points in their disease or <80% follow-up) Systematic review² of Level II studies 	 Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) Systematic review² of Level II studies 	 Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses Systematic review² of Level II studies
Level III	 Case control study⁷ Retrospective⁶ comparative study⁵ Systematic review² of Level III studies 	• Case control study ⁷	 Study of nonconsecutive patients; without consistently applied reference "gold" standard Systematic review² of Level III studies 	 Analyses based on limited alternatives and costs; and poor estimates Systematic review² of Level III studies
Level IV	Case series ⁸	Case series	Case-control studyPoor reference standard	Analyses with no sensitivity analyses

Level V	Expert Opinion	Expert Opinion ypes of Studies	Expert Opinion	Expert Opinion
¹ A complete a	Therapeutic Studies — mized results of treatment assessment of quality of individual studies requested from two or more prior studies.	Prognostic Studies – Investigating the effect of a patient characteristic on the ires critical appraisal of all aspects of the stu outcome of disease	Diagnostic Studies — Investigating a diagnostic test dy design.	Economic and Decision Analyses – Developing an economic or decision model

³Studies provided consistent results.

Grades of Recommendations for Summaries or Reviews of Studies

- A: Good evidence (Level I Studies with consistent finding) for or against recommending intervention.
- B: Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention.
- C: Poor quality evidence (Level IV or V Studies) for or against recommending intervention.
- I: Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Linking Levels of Evidence to Grades of Recommendation

Grade of Recommendation	Standard Language	Levels of Evidence	
A	Recommended	Two or more consistent Level I studies	
В	Suggested	One Level I study with additional supporting Level II or III studies	Two or more consistent Level II or III studies
С	May be considered; is an option	One Level I, II or III study with supporting Level IV studies	Two or more consistent Level IV studies
I (Insufficient or Conflicting Evidence)	Insufficient evidence to make recommendation for or against	A single Level I, II, III or IV study without other supporting evidence	More than one study with inconsistent findings*

^{*}Note that in the presence of multiple consistent studies, and a single outlying, inconsistent study, the Grade of Recommendation will be based on the level of consistent studies.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Isthmic spondylolisthesis

Guideline Category

⁴Study was started before the first patient enrolled.

⁵Patients treated one way (e.g., cemented hip arthroplasty) compared with a group of patients treated in another way (e.g., uncemented hip arthroplasty) at the same institution.

 $^{^6\}mathrm{The}$ study was started after the first patient enrolled.

⁷Patients identified for the study based on their outcome, called "cases" (e.g., failed total arthroplasty) are compared to those who did not have outcome, called "controls" (e.g., successful total hip arthroplasty).

 $^{^{8}}$ Patients treated one way with no comparison group of patients treated in another way.

Diagnosi	

Treatment

Clinical Specialty

Neurological Surgery

Orthopedic Surgery

Intended Users

Physicians

Guideline Objective(s)

- To provide evidence-based recommendations to address key clinical questions surrounding the diagnosis and treatment of adult patients with isthmic spondylolisthesis
- · To assist in delivering optimum, efficacious treatment and functional recovery from isthmic spondylolisthesis

Target Population

Adults (18 years or older) with variable back, lower extremity pain and/or neurologic deficit related to isthmic spondylolisthesis

Interventions and Practices Considered

- 1. Physical examination
 - Positive straight leg test
 - Consideration of radicular lower extremity pain
- 2. Imaging
 - Standing plain radiographs (with or without oblique or dynamic)
 - Computed tomography (CT) scan
 - Magnetic resonance imaging (MRI)
- 3. Surgery
 - Posterolateral fusion
 - 360° fusion
 - Anterior lumbar interbody fusion (ALIF)
 - ALIF with supplemental posterior percutaneous pedicle screws

Note: The following interventions were considered but there was insufficient evidence to make a recommendation for or against:

- Palpation during physical exam
- MRI to differentiate isthmic versus degenerative spondylolisthesis
- $\bullet \;\;$ Use of single-photon emission computerized tomography (SPECT) scan
- Discography to evaluate adult patients with isthmic spondylolisthesis
- Physical therapy/exercise
- Medical/interventional treatment for the long-term management

Major Outcomes Considered

- · Appropriateness and efficacy of diagnostic tests
- Reoperation rates
- Pain and functional disability (Dallas Pain Questionnaire [DPQ] and the Low Back Pain Rating Scale [LBPR])
- · Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Identification of Clinical Questions

Trained guideline participants were asked to submit a list of clinical questions that the guideline should address. The proposed questions were compiled into a master list, which was then circulated to each member for review and comment. A conference call was held to review comments and condense and refine the draft clinical question list. The draft clinical question list was then submitted to the North American Spine Society (NASS) Health Policy and Research Councils for review. The councils submitted additional questions that may be useful for health policy or research purposes and approved the master list.

Identification of Search Terms and Parameters

One of the most crucial elements of evidence analysis is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence and the formulation of evidence-based recommendations. In order to ensure a thorough literature search, NASS has instituted a Literature Search Protocol (see Appendix E in the original guideline document) which has been followed to identify literature for evaluation in guideline development. In keeping with the Literature Search Protocol, work group members have identified appropriate search terms and parameters to direct the literature search. Specific search strategies, including search terms, parameters and databases searched, are documented in the technical report that accompanies this guideline.

Completion of the Literature Search

Once each work group identified search terms/parameters, the literature search was implemented by a medical/research librarian at InfoNOW at the University of Minnesota, consistent with the Literature Search Protocol. Following these protocols ensures that NASS recommendations (1) are based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. NASS maintains a search history in Endnote, for future use or reference.

Literature Search Parameters

Search Strategy

- Medline/PubMed
- The Cochrane Library
- EMBASE
- Duplicate records eliminated
- Humans
- English language
- Date range: All literature to June 2013 (except for natural history question; literature search conducted for all literature to April 2013)
- Adult patients ≥18 years (except for natural history question as including children and adolescents in the literature search was pertinent to addressing the clinical question)
- Review of article references

Inclusion Criteria

• Addresses clinical question

- Isthmic spondylolisthesis patients (if mixed-diagnosis study did not include sub-group analysis of adult isthmic spondylolisthesis patients only, then it was excluded)
- Meta-analysis, randomized controlled trials, prospective clinical trials, prospective and retrospective
- Cohort studies, case-control studies, cross-sectional studies, case-series
- · Peer reviewed journal articles

Exclusion Criteria

- · Mixed diagnosis studies without sub-group analysis of isthmic spondylolisthesis patients
- Narrative reviews, case-reports

Review of Search Results/Identification of Literature to Review

Work group members reviewed all abstracts yielded from the literature search and identified the literature they will review in order to address the clinical questions, in accordance with the Literature Search Protocol. Members have identified the best research evidence available to answer the targeted clinical questions. That is, if Level I, II and or III literature is available to answer specific questions, the work group was not required to review Level IV or V studies.

Number of Source Documents

Articles meeting inclusion criteria and included in guideline:

- Natural History: 3
- Diagnosis/Imaging: 18
- Medical/Interventional Treatment: 4
- Surgical Treatment: 28

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence for Primary Research Question¹

Types of Studies				
	Therapeutic Studies — Investigating the results of treatment	Prognostic Studies — Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies — Investigating a diagnostic test	Economic and Decision Analyses — Developing an economic or decision model
Level I	 High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals Systematic review² of Level I RCTs (and study results were homogenous³) 	 High quality prospective study⁴ (all patients were enrolled at the same point in their disease with ≥80% follow-up of enrolled patients) Systematic review² of Level I studies 	 Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) Systematic review² of Level I studies 	Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses Systematic review ² of Level I studies
	Lesser quality RCT (e.g.,	Retrospective ⁶ study	Development of	Sensible costs

Level II	<80% follow-up, no	Untreaf Types to 6 Is findings	diagnostic criteria on	and alternatives;
	blinding, or improper The rapeutic Studies – Investigating the results of Prospective comparative treatment study Systematic review ² of Level II studies or Level I	Propositic Studies – Lesser quality Investigating the effect of a prospective study (e.g. patient characteristic on the patients enrolled at outcome of disease different points in their disease or <80% follow-	consecutive patients Diagnostic Studies – Investigating a diagnostic "gold" standard) • Systematic review ² of Level II studies	values obtained Economic and Decision Analyses — Developing an economic or decision analyses • Systematic
	studies with inconsistent results	up) • Systematic review ² of Level II studies		review ² of Level II studies
Level III	 Case control study⁷ Retrospective⁶ comparative study⁵ Systematic review² of Level III studies 	• Case control study ⁷	 Study of nonconsecutive patients; without consistently applied reference "gold" standard Systematic review² of Level III studies 	 Analyses based on limited alternatives and costs; and poor estimates Systematic review² of Level III studies
Level IV	Case series ⁸	Case series	Case-control studyPoor reference standard	Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

RCT = randomized controlled trial

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Evidence Analysis

Members have independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses and assigning levels of evidence. In order to systematically control for potential biases, at least two work group members have reviewed each article selected and independently assigned levels of evidence to the literature using the North American Spine Society (NASS) levels of evidence. Any discrepancies in scoring have been addressed by two or more reviewers. Final ratings are completed at a final meeting or Web conference of all section workgroup members including the section chair and the guideline chair. The consensus level was then assigned to the article. Multi-diagnosis studies that did not include sub-group analysis of isthmic spondylolisthesis patients failed to meet inclusion criteria and were excluded

¹A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

²A combination of results from two or more prior studies.

³Studies provided consistent results.

⁴Study was started before the first patient enrolled.

⁵Patients treated one way (e.g., cemented hip arthroplasty) compared with a group of patients treated in another way (e.g., uncemented hip arthroplasty) at the same institution.

⁶The study was started after the first patient enrolled.

⁷Patients identified for the study based on their outcome, called "cases" (e.g., failed total arthroplasty) are compared to those who did not have outcome, called "controls" (e.g., successful total hip arthroplasty).

⁸Patients treated one way with no comparison group of patients treated in another way.

from the guideline.

As a final step in the evidence analysis process, members have identified and documented gaps in the evidence to educate guideline readers about where evidence is lacking and help guide further needed research by NASS and other societies.

Levels of Evidence

In evaluating studies as to levels of evidence for this guideline, the study design was interpreted as establishing only a potential level of evidence. As an example, a therapeutic study designed as a randomized controlled trial would be considered a potential Level I study. The study would then be further analyzed as to how well the study design was implemented and significant shortcomings in the execution of the study would be used to downgrade the levels of evidence for the study's conclusions. In the example cited previously, reasons to downgrade the results of a potential Level I randomized controlled trial to a Level II study would include, among other possibilities: an underpowered study (patient sample too small, variance too high), inadequate randomization or masking of the group assignments and lack of validated outcome measures.

In addition, a number of studies were reviewed several times in answering different questions within this guideline. How a given question was asked might influence how a study was evaluated and interpreted as to its level of evidence in answering that particular question. For example, a randomized controlled trial reviewed to evaluate the differences between the outcomes of surgically treated versus untreated patients with lumbar disc herniation with radiculopathy might be a well designed and implemented Level I therapeutic study. This same study, however, might be classified as providing Level II prognostic evidence if the data for the untreated controls were extracted and evaluated prognostically.

Methods Used to Formulate the Recommendations

Expert Consensus (Nominal Group Technique)

Description of Methods Used to Formulate the Recommendations

Identification of Work Groups

Multidisciplinary teams were assigned to work groups and assigned specific clinical questions to address. Because NASS is comprised of surgical, medical and interventional specialists, it is imperative to the guideline development process that a cross-section of NASS membership is represented on the work group. This also helps to ensure that the potential for inadvertent biases in evaluating the literature and formulating recommendations is minimized.

Formulation of Evidence-Based Recommendations and Incorporation of Expert Consensus

Work groups held Web conferences and face-to-face meetings to discuss the evidence-based answers to the clinical questions, the grades of recommendations and the incorporation of expert consensus. Expert consensus was incorporated only where Level I to IV evidence is insufficient and the work group has deemed that a recommendation is warranted. Transparency in the incorporation of consensus is crucial, and all consensus-based recommendations made in this guideline very clearly indicate that Level I to IV evidence is insufficient to support a recommendation and that the recommendation is based only on expert consensus.

Consensus Development Process

Voting on guideline recommendations was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 ("extremely inappropriate") to 9 ("extremely appropriate"). Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8 or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted.

After the recommendations were established, work group members developed the guideline content, addressing the literature supporting the recommendations.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendations for Summaries or Reviews of Studies

A: Good evidence (Level I Studies with consistent finding) for or against recommending intervention.

- B: Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention.
- C: Poor quality evidence (Level IV or V Studies) for or against recommending intervention.
- I: Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Linking Levels of Evidence to Grades of Recommendation

Grade of Recommendation	Standard Language	Levels of Evidence	
A	Recommended	Two or more consistent Level I studies	
В	Suggested	One Level I study with additional supporting Level II or III studies	Two or more consistent Level II or III studies
С	May be considered; is an option	One Level I, II or III study with supporting Level IV studies	Two or more consistent Level IV studies
I (Insufficient or Conflicting Evidence)	Insufficient evidence to make recommendation for or against	A single Level I, II, III or IV study without other supporting evidence	More than one study with inconsistent findings*

^{*}Note that in the presence of multiple consistent studies, and a single outlying, inconsistent study, the Grade of Recommendation will be based on the level of consistent studies.

Cost Analysis

The guideline developers reviewed published cost analyses (see Section F, "Value/Cost-effectiveness," in the original guideline document). Due to the paucity of evidence, a recommendation could not be made regarding the cost-effectiveness of medical/interventional treatment for the management of patients with isthmic spondylolisthesis. There was also insufficient evidence to make a recommendation for or against the cost-effectiveness of surgical treatments for isthmic spondylolisthesis.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Submission of the Draft Guidelines for Review/Comment

Guidelines were submitted to the full Evidence-Based Guideline Development Committee and the Research Council for review and comment. Revisions to recommendations were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

Submission for Board Approval

Once any evidence-based revisions were incorporated, the drafts were prepared for North American Spine Society (NASS) Board review and approval. Edits and revisions to recommendations and any other content were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Assisting practitioners in their clinical decision making processes in the diagnosis and effective treatment of adult isthmus spondylolisthesis

Potential Harms

Surgical procedures for adult isthmic spondylolisthesis carry the risk of complications including deep wound infections, permanent and transient leg pain, pulmonary embolism, foot drops, postoperative paraparesis, permanent L5 injuries, pain in the bone graft donor site, nonunion, implant removals, nerve root injuries, and transient paralytic ileus.

Qualifying Statements

Qualifying Statements

- This guideline does not represent a "standard of care," nor is it intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside this guideline will sometimes be necessary. This guideline should not be seen as prescribing the type, frequency or duration of intervention. Treatment should be based on the individual patient's need and doctor's professional judgment and experience. This document is designed to function as a guideline and should not be used as the sole reason for denial of treatment and services. This guideline is not intended to expand or restrict a health care provider's scope of practice or to supersede applicable ethical standards or provisions of law.
- This clinical guideline should not be construed as including all proper methods of care or excluding or other acceptable methods of care
 reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the
 physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

Implementation of the Guideline

Description of Implementation Strategy

These guidelines are developed for educational purposes to assist practitioners in their clinical decision making processes. It is anticipated that where evidence is very strong in support of recommendations, these recommendations will be operationalized into performance measures.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

North American Spine Society (NASS). Diagnosis and treatment of adult isthmic spondylolisthesis. Burr Ridge (IL): North American Spine Society (NASS); 2014. 87 p. [488 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014

Guideline Developer(s)

North American Spine Society - Medical Specialty Society

Source(s) of Funding

This clinical guideline was developed and funded in its entirety by the North American Spine Society (NASS).

Guideline Committee

North American Spine Society (NASS) Evidence-Based Clinical Guidelines Committee

Composition of Group That Authored the Guideline

Committee Members: D. Scott Kreiner, MD (Committee Co-chair and Natural History Section Chair); Jamie Baisden, MD (Diagnosis/Imaging Section Chair); Daniel Mazanec, MD (Medical/Interventional Treatment Section Chair); Rakesh Patel, MD (Surgical Treatment Section Chair); Robert Shay Bess, MD (Value Section Chair); Douglas Burton, MD; Norman B. Chutkan, MD; Bernard A. Cohen, PhD; Charles H. Crawford III, MD; Gary Ghiselli, MD; Amgad S. Hanna, MD; Steven W. Hwang, MD; Cumhur Kilincer, MD, PhD; Mark E. Myers, MD; Paul Park, MD; Anil K. Sharma, MD; Christopher K. Taleghani, MD; Terry R. Trammel, MD; Andrew N. Vo, MD; Keith D. Williams, MD

Financial Disclosures/Conflicts of Interest

Disclosure of Potential Conflicts of Interest

All participants involved in guideline development have disclosed potential conflicts of interest to their colleagues in accordance with North American Spine Society (NASS) Disclosure Policy for committee members and their potential conflicts have been documented in the original guideline document. NASS does not restrict involvement in guidelines based on conflicts as long as members provide full disclosure. Individuals with a conflict relevant to the subject matter were asked to recuse themselves from deliberation. Participants have been asked to update their disclosures regularly throughout the guideline development process.

Please see the "Financial Statement" section in the original guideline document for a complete list of disclosures.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the North American Spine Society (NASS) Web site

Availability of Companion Documents

The following is available:

• North American Spine Society evidence-based guidelines: diagnosis and treatment of adult isthmic spondylolisthesis. Technical report. Burr Ridge (IL): North American Spine Society (NASS); 2014. 170 p. Available in from the North American Spine Society (NASS) Web site

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on November 2, 2015.

Copyright Statement

Full-text guidelines can only be acquired through the North American Spine Society (NASS). Questions regarding use and reproduction should be directed to NASS, attention Belinda Duszynski, Research Manager.

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ, & (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.